Rules and Regulations

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–325F]

Schedules of Controlled Substances: Placement of Lacosamide into Schedule V

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the DEA places the substance lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide] and any material, compound, mixture, or preparation which contains any quantity of lacosamide into schedule V of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule V will be applicable to the manufacture, distribution, dispensing, importation and exportation of lacosamide.

DATES: *Effective Date:* This rule is effective June 22, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

On October 28, 2008, the Food and Drug Administration (FDA) approved lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide] for marketing under the trade name Vimpat® for use as an adjunctive therapy in treatment of partial-onset seizures in patients with epilepsy ages 17 years and older.

On December 2, 2008, the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) sent the Administrator of the DEA a scientific and medical evaluation and a letter recommending that lacosamide be placed into schedule V of the CSA. Enclosed with the December 2, 2008, letter was a document prepared by the FDA entitled "Basis for the Recommendation for Control of Lacosamide in Schedule V of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

Based on the recommendation of the Assistant Secretary for Health and an independent review of the available data by the DEA, the Deputy Administrator of the DEA, in a March 10, 2009, Notice of Proposed Rulemaking (74 FR 10205) proposed placement of lacosamide into schedule V of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before April 9, 2009.

Comments Received

DEA received one comment within the comment period in response to the Notice of Proposed Rulemaking. The commenter stated that lack of information and inappropriate comparisons to other drugs precluded the scheduling of lacosamide and suggested that scheduling be postponed for 24 months to collect data.

DEA does not agree. The studies used to assess abuse potential of lacosamide are widely held as the standard methods of evaluation. Behavioral effects of lacosamide in animals and humans were found to be similar to, but transient relative to, those of the schedule IV drugs alprazolam and phenobarbital. Preclinical studies indicated that lacosamide is self-administered at rates higher than saline and partially mimics discrimitive stimulus effects to the schedule IV substances alprazolam and phenobarbital. In clinical trials, lacosamide produced subjective responses similar to alprazolam but these effects did not last as long as alprazolam. After careful consideration of positive indicators from preclinical and clinical studies, DEA finds lacosamide has abuse potential supporting placement in schedule V under the CSA. The DHHS recommended control in schedule V of the CSA and the DEA concurs.

The commenter also submitted a request for a hearing. DEA regulations provide that "[a]ny interested person" may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811]." 21 CFR 1300.01(b)(19). The regulations further require that any person requesting a hearing must state "with particularity" his interest in the proceeding. 21 CFR 1316.47(a). The commenter failed to provide sufficient information to demonstrate that he meets the definition of "interested person" as set forth in the regulations, therefore DEA is denying his hearing request.

DEA also received many comments after the comment period closed. These late comments were not considered by DEA.

Scheduling of Lacosamide

Based on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Lacosamide has a low potential for abuse relative to the drugs or other substances in schedule IV;

(2) Lacosamide has a currently accepted medical use in treatment in the United States; and

(3) Abuse of lacosamide may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Based on these findings, the Deputy Administrator of the DEA concludes that lacosamide and any material, compound, mixture, or preparation which contains any quantity of lacosamide, warrant control in schedule V of the CSA.

Requirements for Handling Lacosamide

Registration. Any person who manufactures, distributes, dispenses,

imports, exports, engages in research or conducts instructional activities with lacosamide, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lacosamide, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations (CFR). Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 22, 2009 and may continue their activities until the DEA has approved or denied the application.

Security. Lacosamide is subject to schedule III–V security requirements and must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the CFR on and after June 22, 2009.

Labeling and Packaging. All labels and labeling for commercial containers of lacosamide which are distributed on or after June 22, 2009 must comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of lacosamide must keep an inventory of all stocks of lacosamide on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the CFR on or after June 22, 2009. Every registrant who desires registration in schedule V for lacosamide must conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Prescriptions. All prescriptions for lacosamide pharmaceutical products must be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.23–1306.27 on or after June 22, 2009.

Importation and Exportation. All importation and exportation of lacosamide must be in compliance with part 1312 of Title 21 of the CFR on or after June 22, 2009.

Criminal Liability. Any activity with lacosamide not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act occurring on or after June 22, 2009 shall be unlawful.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, § 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Lacosamide pharmaceutical products will be prescription drugs used for the treatment of partial-onset seizures. Handlers of lacosamide often handle other controlled substances used in the treatment of central nervous system disorders which are already subject to the regulatory requirements of the CSA.

Executive Order 12988

This regulation meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to Title 28, Part 0, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

■ 2. Section 1308.15 is amended by revising paragraph (e)(1) and adding a new paragraph (e)(2) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(e) * * *

(1) Lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide]—2746

(2) Pregabalin [(*S*)-3-(aminomethyl)-5-methylhexanoic acid]—2782

Dated: May 12, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–11927 Filed 5–20–09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–319F]

Schedules of Controlled Substances: Placement of Tapentadol Into Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance tapentadol, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, into schedule II of the

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Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation, and exportation of tapentadol and products containing tapentadol.

DATES: *Effective Date:* June 22, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

On November 20, 2008, the Food and Drug Administration (FDA) approved tapentadol for marketing in the United States as a prescription drug product for the treatment of moderate-to-severe acute pain. Tapentadol is a new molecular entity with centrally-acting analgesic properties.

Tapentadol has dual modes of action, namely mu (μ) opioid receptor agonistic action and inhibition of reuptake of norepinephrine at the norepinephrine transporter. The chemical name of its monohydrochloride salt form is 3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride. Tapentadol shares substantial pharmacological effects and abuse potential with other schedule II opioid analgesics, *e.g.*, morphine, oxycodone, and hydromorphone.

Since tapentadol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On November 13, 2008, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that tapentadol be placed into schedule II of the CSA. Enclosed with the November 13, 2008, letter was a document prepared by the Food and Drug Administration (FDA) entitled, "Basis for the Recommendation for Control of Tapentadol in Schedule II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of Tapentadol into Schedule II" on February 17, 2009 (74 FR 7386), which proposed placement of tapentadol into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before March 19, 2009.

Comments Received

The DEA received three comments in response to the Notice of Proposed Rulemaking. One comment was from a consulting firm, one comment was from a concerned citizen, and the last comment was from a company which does research and development on pharmaceutical drugs.

The first commenter recommended that the DEA expedite the issuance and effective date of the Final Rule placing tapentadol in schedule II. The commenter stated that tapentadol will provide a safe and effective substitute for other schedule II analgesics and that the conditions of public health necessitate and justify this request. In response, DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with the regulatory requirements for handling schedule II controlled substances.

A second commenter stated that since tapentadol induces effects similar to oxycodone and morphine, both schedule II substances, then it should be placed in schedule II of the Controlled Substances Act based on tapentadol's abuse potential. Thus, the commenter agreed with DHHS' recommendation and the action proposed by DEA. No response from DEA is necessary to this comment because it is consistent with the DEA's final action.

The third commenter had four questions/comments regarding the implementation of this Final Rule. Each question/comment is addressed below.

The commenter requested that DEA registrants be allowed enough time to make the changes needed to carry out handling tapentadol as a schedule II substance, as dictated in 21 CFR 1301.51, 1301.71, and 1304.04. In response to this comment, the effective date of the Final Rule placing tapentadol in schedule II of the Controlled Substances Act will be thirty (30) days from the date of publication of the Final Rule, thus allowing ample time for those that wish to handle tapentadol to meet DEA regulatory requirements for handling schedule II substances. It has been DEA's experience that this is sufficient time to meet the regulatory requirements provided below.

The commenter asked if quantities of tapentadol held by a DEA registrant would have to be reported once the scheduling of tapentadol as a schedule II substance was finalized. In response, the reporting and recordkeeping requirements for handling schedule II substances can be found in 21 CFR part 1304. Specifically, 21 CFR 1304.11(b) states that "Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances * * *" In order for a manufacturer to handle a schedule II substance, a manufacturing or procurement quota has to be requested in accordance with the requirements of 21 U.S.C. 826(c) and 21 CFR part 1303. The manufacturer's inventory of the substance is used, in part, to determine the manufacturer's quota.

The commenter asked about the process for adding the CSA drug code for tapentadol to their registration. In response, the regulatory process required to obtain a DEA registration is outlined generally in 21 CFR 1301.11 through 1301.19, and the process required to modify an existing DEA registration is outlined in 21 CFR 1301.51. Information relating to registration may be found on the Internet, *http://www.DEAdiversion.usdoj.gov*, or by contacting DEA's Registration Call Center, toll free at 1–800–882–9539.

Finally, the commenter inquired about the process for establishing an NDC number for tapentadol with the Automation of Reports and Consolidated Orders System (ARCOS). National Drug Code (NDC) numbers are assigned by the Food and Drug Administration (FDA) in conjunction with registration and drug listing requirements of the Federal Food, Drug, and Cosmetic Act. Accordingly, a person manufacturing a product containing tapentadol must obtain an NDC number from FDA in accordance with 21 CFR 207.35. Once the drug code for tapentadol is added to an existing manufacturer's registration or a new registration is issued to an applicant, then that DEA-registered manufacturer must provide the DEA's ARCOS Unit with its established NDC number for their product containing tapentadol. Once that information is obtained, it can be used to report ARCOS reportable transactions pursuant to 21 CFR 1304.33.

Scheduling of Tapentadol

Based on the recommendation of the Assistant Secretary for Health, received

in accordance with § 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to §§ 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Tapentadol has a high potential for abuse;

(2) Tapentadol has a currently accepted medical use in treatment in the United States; and

(3) Abuse of tapentadol may lead to severe psychological or physical dependence.

Based on these findings, the Deputy Administrator of DEA concludes that tapentadol, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrants control in schedule II of the CSA (21 U.S.C. 812(b)(2)).

Requirements for Handling Tapentadol

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with tapentadol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with tapentadol, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 22, 2009 and may continue their activities until DEA has approved or denied that application.

Security. Tapentadol is subject to schedule II security requirements and must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Labeling and Packaging. All labels and labeling for commercial containers of tapentadol must comply with requirements of §§ 1302.03 through 1302.07 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Quotas. Quotas for tapentadol must be established pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of tapentadol must keep an inventory of all stocks of tapentadol on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after June 22, 2009. Every registrant who desires registration in schedule II for tapentadol must conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Reports. All registrants required to submit reports to the Automation of Reports and Consolidated Order System (ARCOS) in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations must do so for tapentadol.

Orders for Tapentadol. All registrants involved in the distribution of tapentadol must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Prescriptions. All prescriptions for tapentadol or prescriptions for products containing tapentadol must be issued pursuant to §§ 1306.03 through 1306.06 and 1306.11 through 1306.15 of Title 21 of the Code of Federal Regulations on and after June 22, 2009.

Importation and Exportation. All importation and exportation of tapentadol must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Criminal Liability. Any activity with tapentadol not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after June 22, 2009.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Tapentadol products will be prescription drugs used for the treatment of moderate-to-severe acute pain. Handlers of tapentadol also handle other controlled substances used to treat pain which are already subject to the regulatory requirements of the CSA.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to Title 28, Part 0, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

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PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.12 is amended in the table by adding a new paragraph (c)(28) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(28) Tapentadol	9780

* * * * *

Dated: May 15, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–11933 Filed 5–20–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0089]

RIN 1625–AA00

Safety Zone; Red Bull Air Race, Detroit River, Detroit, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Detroit River, Detroit, Michigan. This zone will restrict vessels from portions of the Detroit River during the Red Bull Air Race. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with air races.

DATES: This rule is effective from 9 a.m. on June 11, 2009 through 6:30 p.m. on June 14, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0089 and are available online by going to *http://www.regulations.gov*, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0089 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail CDR Joseph Snowden, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568–9580, e-mail *Joseph.H.Snowden@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 16, 2009, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Red Bull Air Race, Detroit River, Detroit, MI in the **Federal Register** (74 FR 17627). We received one comment on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring, to the extent practicable, the safety and security of the spectators and participants during this event and immediate action is necessary to prevent possible injury, loss of life, or property.

Background and Purpose

This temporary safety zone is necessary to ensure, to the extent practicable, the safety of vessels and spectators from hazards associated with an air race. The Captain of the Port Detroit has determined air races in close proximity to watercraft and infrastructure pose significant risk to public safety and property. The likely combination of large numbers of recreation vessels, possible alcohol use, airplanes traveling at high speeds and performing aerial acrobatics, and large numbers of spectators in close proximity to the water could easily result in serious injuries or fatalities. Establishing a safety zone around the location of the race course will help ensure the safety of persons and property at these events and help minimize the associated risks.

Discussion of Comments and Changes

We received one letter, containing several comments on this rulemaking. First, the commenter stated that closure of the Detroit River for these air races violates the Boundary Waters Treaty of 1909. The Coast Guard disagrees that the Coast Guard's action or the action by Canada violates this treaty. The Boundary Waters Treaty does guarantee that "navigation of all navigable boundary waters" shall be "free and open" to "inhabitants * * * ships, vessels, and boats" of both the United States and Canada, "subject, however, to any laws and regulations of either country." Both the United States and Canada have determined, pursuant to each country's laws and regulations, that brief closures of the Detroit River are reasonably necessary to protect spectators and vessels from hazards associated with these air races. Moreover, under fundamental principles of international law, only the States that are a party to an international agreement are generally entitled to allege a breach of the terms of the agreement by the other. For this event, Canada has also agreed that a closure of a small portion of the river for a short period of time is a reasonable and necessary measure.

Second, the commenter stated that the proposed rule constituted a "public taking" in contravention of the Fifth Amendment to the United States Constitution; in that vessel owners will experience delays that will result in lost profits. This commenter did not put forward any specific company or vessel that would be so affected. The Coast Guard disagrees with this comment. In general, a "taking" occurs when a governmental entity uses its powers to permanently deprive a person or entity of property. The Captain of the Port has considered the needs of port stakeholders and the maritime community and has determined that this safety zone is necessary to protect the public and maintain safety of navigation. Further, the rule is only temporary in nature, not permanent, and in the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Detroit to transit through the safety zone. Moreover, the safety zone will only be enforced for a short period of time on the enforcement dates. Lastly, the Coast Guard believes vessel owners have had sufficient advance notice of this safety zone, such that they should be able to work vessel schedules around the enforcement periods of the proposed safety zone to minimize or avoid lost profits.

Third, the commenter stated that the race sponsor must be required to agree in advance to reasonably compensate vessel owners for losses incurred by delays and post a bond sufficient to cover anticipated vessel losses. Otherwise, this commenter stated, there is no incentive for race organizers to work collaboratively with vessel

Agenda Item: **Review of Legislative Proposal**

Included in the agenda package:

A copy of the draft amendments to the Code of Virginia submitted by the Office of Community Integration for People with Disabilities

Action: No action is required; this is not DHP or Board of Pharmacy legislation. The Office is seeking any comment or concerns that the Board might have.

Medical Practice Act

Revised April 28, 2009

(Medicine and Other Healing Arts)

§ 54.1-2901. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;

2. Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;

3. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;

4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine;

5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;

6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;

7. The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state to emergency medical personnel acting in an emergency situation;

8. The domestic administration of family remedies;

9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;

10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a practitioner of the healing arts who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state;

28. Any registered nurse, acting as an agent of the Department of Health, from obtaining specimens of sputum or other bodily fluid from persons in whom the diagnosis of active tuberculosis disease, as defined in § 32.1-49.1, is suspected and submitting orders for testing of such specimens to the Division of Consolidated Laboratories or other public health laboratories, designated by the State Health Commissioner, for the purpose of determining the presence or absence of tubercle bacilli as defined in § 32.1-49.1;

29. Any physician of medicine or osteopathy or nurse practitioner from delegating to a registered nurse under his supervision the screening and testing of children for elevated blood-lead levels when such testing is conducted (i) in accordance with a written protocol between the physician or nurse practitioner and the registered nurse and (ii) in compliance with the Board of Health's regulations promulgated pursuant to §§ 32.1-46.1 and 32.1-46.2. Any follow-up testing or treatment shall be conducted at the direction of a physician or nurse practitioner;

30. Any practitioner of one of the professions regulated by the Board of Medicine who is in good standing with the applicable regulatory agency in another state or Canada from engaging in the practice of that profession when the practitioner is in Virginia temporarily with an out-of-state athletic team or athlete for the duration of the athletic tournament, game, or event in which the team or athlete is competing; or

31. Any licensed nurse practitioner in the category of certified nurse midwife from rendering care in collaboration and consultation with a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing.

32. Any person from performing consumer-directed health care tasks, which are typically self-performed, for an individual who lives in a private residence and who, by reason of disability, is unable to perform such tasks but who is capable of directing the appropriate performance of such tasks.

B. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife may practice without the requirement for physician supervision while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.

(Code 1950, §§ 54-273, 54-274, 54-276 through 54-276.6; 1950, pp. 98, 110; 1954, c. 556; 1958, c. 161; 1960, c. 268; 1962, cc. 127, 394; 164, c. 317; 1966, c. 657; 1970, c. 69; 1973, cc. 105, 514, 529; 1975, cc. 508, 512; 1976, c. 15; 1977, c. 127; 1980, c. 157; 1981, c. 300; 1982, c. 220; 1985, cc. 303, 347, 372; 1986, cc. 377, 439; 1987, cc. 522,

P. Nothing in this title shall prohibit the administration of normally self-administered ~~oral or topical~~ drugs by unlicensed individuals to a person in his private residence.

Q. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

R. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) of this title, in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) of this title.

S. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

T. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

U. A nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Virginia Department of Health.

(Code 1950, § 54-497; 1956, c. 225; 1970, c. 650, § 54-524.65; 1973, c. 468; 1976, cc. 358, 614; 1977, c. 302; 1978, c. 224; 1980, cc. 270, 287; 1983, cc. 456, 528; 1984, cc. 141, 555; 1986, c. 81; 1987, c. 226; 1988, c. 765; 1990, c. 309; 1991, cc. 141, 519, 524,

Board of Pharmacy

Current Regulatory Actions

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Drug donation program Stage: Emergency/NOIRA - *Register Date: 4/27/09* *Emergency regulation effective 4/10/09 to 4/9/10* *Close of comment on NOIRA – 5/27/09* *Adoption of proposed regulation – 6/10/09*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Changes in renewal dates for pharmacies and permitted facilities Stage: Proposed - *Register Date: 6/8/09* *Public hearing – 6/10/09* *Comment closes – 8/7/09*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Standards of conduct Stage: Proposed - *At Governor's Office*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Periodic review Stage: Final - *At Governor's Office*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Address of record/public address Stage: Final - *Register Date: 4/27/09* *Effective 7/1/09*

Agenda Item: **Regulatory Action – Adoption of Proposed Regulations**

Registration of Drug Donation Sites

Staff Note: Included in your package are copies of:

A copy of the 2009 legislation with amended language of § 54.1-3411.1

There was no public comment on Notice of Intended Regulatory Action

A copy of draft proposed regulations for registration of drug donation sites. Proposed regulations are identical to emergency regulations in effect between April 10, 2009 and April 9, 2010

Action:

Motion for adoption of proposed regulations.

093269592

HOUSE BILL NO. 2352

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare, and Institutions on January 27, 2009)

(Patron Prior to Substitute—Delegate Landes)

A BILL to amend and reenact § 54.1-3411.1 of the Code of Virginia, relating to donation of prescription medication; liability of pharmaceutical manufacturers.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3411.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or

3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

B. (For contingent expiration - see Editor's note) Pursuant to a voluntary agreement between a nursing home or a hospital and a pharmacy, drugs may be transferred in accordance with subdivision A 2 between the nursing home or the hospital and the pharmacy for re-dispensing to patients of clinics organized in whole or in part for the delivery of health care services without charge, or to the indigent, free of charge, if the following procedures are satisfied:

1. The physical transfer shall be accomplished by a person authorized to do so by the pharmacy;

2. The person or his authorized representative from whom the prescription medication was obtained shall provide written consent for the donation and such consent shall be maintained on file at the licensed nursing home or hospital;

3. The person's name, prescription number, and any other patient identifying information, shall be obliterated from the packaging prior to removal from the licensed nursing home or hospital;

4. The drug name, strength, and expiration date or beyond-use date shall remain on the medication package label;

5. An inventory list of the drugs shall accompany the drugs being transferred that shall include, but not be limited to, the medication names, strengths, expiration dates, and quantities; and

6. Outdated drugs shall not be transferred and shall be destroyed in accordance with regulations adopted by the Board.

The pharmacist-in-charge at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no product shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured.

B. (For contingent effective date - see Editor's note) The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A2, for the purpose of re-dispensing such drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured.

C. ~~Nothing in this section shall authorize the donation of unused~~*Unused* prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, *may be donated pursuant to this section unless such donation is prohibited.*

D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the ~~transfer of any prescription or any consumer information regarding the transferred prescription medication pursuant to this section.~~*storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient, or any other activity undertaken in accordance with a drug distribution program established pursuant to this section*

E. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in

accordance with a drug distribution program established pursuant to this section.

Draft Proposed Regulations
Identical to Emergency Regulations – Effective 4/10/09 to 4/9/10

BOARD OF PHARMACY
Drug donation program

Part I
General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the Virginia Board of Pharmacy for the purpose of receiving or re-dispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

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"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted from a practitioner authorized to prescribe directly to a pharmacy without interception or intervention from a third party, or from one pharmacy to another pharmacy.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for continuous monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-400. Returning of drugs and devices.

~~A.~~ Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of § 54.1-3411.1 of the Code of Virginia. Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

~~B. Any pharmacy accepting drugs returned from nursing homes for the purpose of redispensing to the indigent free of charge shall maintain a copy of a written agreement with the nursing home in accordance with § 54.1-3411.1 B of the Code of Virginia and a current policy and procedure manual describing the following:~~

~~1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;~~

~~2. Procedure for determining the suitability and integrity of drugs for redispensing to include assurance that the drugs have been stored according to official compendial standards; and~~

~~3. Procedure for assigning a beyond-use date on redispensed drugs.~~

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18VAC110-20-740. Drug donation sites.

Any pharmacy with a current active pharmacy permit may apply on a form provided by the board for registration as a drug donation site. A registered drug donation site may receive eligible donated drugs, transfer such donated drugs to another registered drug donation site, or re-dispense the donated drugs in accordance with § 54.1-3411.1 of the Code of Virginia to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Drugs collected under the drug donation program may not be dispensed to any other patient, sold, or otherwise distributed except as authorized in 18VAC110-20-770 or 18VAC110-20-790.

18VAC110-20-750. Eligible drugs.

A. Drugs may be accepted by a registered drug donation site only if the following criteria are met:

1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, as set forth in § 54.1-3411.1, subdivision A2;

2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and

3. The drugs have not been adulterated or misbranded.

B. The following drugs shall not be accepted by a drug donation site:

1. Schedule II-V controlled substances or any other drug, if such return is inconsistent with federal law;

2. Drugs determined to be hazardous for donation based on the pharmacist's professional judgment, experience, knowledge, or available reference materials;

3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and

4. Drugs that have been previously compounded.

18VAC110-20-760. Procedures for collecting eligible donated drugs.

A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long term care facility or other facility where drugs are administered to that patient, if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed;

2. A statement that the donor intends to voluntarily donate the prescription drug for re-dispensing;

3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements;

4. Contact information of the patient or patient's agent;

5. The date of donation;

6. A listing of the donated drugs to include name, strength, and quantity;

7. A statement that private health information will be protected;

8. The signature of the patient or patient's agent; and

9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.

D. Donated prescription drugs shall be stored within the prescription department, separate from other drug inventory.

E. Prior to transferring any donated drugs or re-dispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable.

E. A drug donation site may not charge a fee for collecting donated drugs.

18VAC110-20-770. Procedure for transferring donated prescription drugs.

A. A drug donation site may transfer eligible donated prescription drugs to another drug donation site for the purpose of re-dispensing.

B. The transferring drug donation site shall provide a transfer record to the receiving drug donation site that includes the following:

1. The names and addresses of the transferring site and the receiving site;

2. The name, strength, and quantity of each donated drug being transferred; and

3. The date of transfer.

C. The original transfer record shall be maintained by the transferring drug donation site.

D. A copy of the transfer record shall be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and it shall be maintained by the receiving drug donation site.

18VAC110-20-780. Procedure for dispensing donated prescription drugs.

A. A drug donation site re-dispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.

B. The pharmacy re-dispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug re-dispensed, consistent with provisions of subdivision 10 of § 54.1-3301.

C. Recipients of a re-dispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for the purpose of re-dispensing pursuant to § 54.1-3411.1. The drug donation site shall maintain this form.

D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.

18VAC110-20-790. Procedures for disposing of donated prescription drugs.

A. A drug donation site in possession of donated prescription drugs ineligible for re-dispensing shall dispose of such drugs in compliance with 18 VAC110-20-210.

B. A drug donation site shall maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.

18VAC110-20-800. Records.

A. All records required for drug donation programs shall be maintained chronologically for two years.

B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records.

C. Storage of records.

1. Transfer, dispensing, and disposal records may be stored in an electronic database or record;

2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image which provides an exact, clearly legible, image of the document; or

3. Records may be stored in secured storage, either on or offsite.

D. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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Agenda Item: **Response to Petition for rulemaking**

Staff Note: A petition for rulemaking was received from Eric Hampton. It was published on April 13, 2009 with comment requested until May 13, 2009.

Enclosed are:

A copy of the petition and the notice in the Register of Regulations

A copy of the comments received on the Va. Regulatory Townhall

Action: To accept the petitioner's request and initiate rulemaking or to reject the request. Reasons for the decision must be stated.

BOARD OF PHARMACY

Initial Agency Notice

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy.**

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Name of Petitioner: Eric D. Hampton.

Nature of Petitioner's Request: Amend regulations pertaining to automated devices for dispensing and administration of drugs to use the activity reports rather than having a nurse or other licensed person sign for the delivery.

Agency's Plan for Disposition of Request: The board will receive public comment on the petition for rulemaking until May 13, 2009, and will review the petition and any comments at its meeting on June 10, 2009, to make a decision on whether to initiate rulemaking.

Public Comments: Comments may be submitted until May 13, 2009.

Agency Contact: Elizabeth Scott Russell, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Richmond, VA 23233, telephone (804) 662-9911, FAX (804) 662-9313, or email scotti.russell@dhp.virginia.gov.

VA.R. Doc. No. R09-14; Filed March 13, 2009, 2:23 p.m.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle Initial, Suffix,) Hampton, Eric D.		
Street Address 11701 Old Nuckols Rd.	**Area Code and Telephone Number** 804-364-1569	
City Glen Allen	**State** VA	**Zip Code** 23059
Email Address (optional)	**Fax (optional)**	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18VAC110-20-490. Automated devices for dispensing and administration of drugs.

2. At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated or maintained electronically provided the system being used has the capability of recording an electronic signature which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a read-only format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard-copy printout of the record upon request.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.
Amend requirement for having a nurse or other person sign for medications being loaded into automated device for Hospitals. This requirement has created a hard ship on nurses as the nursing shortage continues. Pulling nurses from patient care to sign for medications is clinically irresponsible. It also provides no evidence or control that meds were actually loaded into the device since the requirement doesn't require the nurse to watch the meds being loaded into the device. Hospital pharmacies utilize activity reports that verify meds were actually loaded into the device. These reports are more reliable and provide accountability; and most hospitals have a manager or narcotic tech review these reports daily. I am petitioning the Board of Pharmacy to allow exemption for hospitals to utilize hospital activity reports in lieu of having nursing sign for medications at the time of loading into an automated device. This will allow nursing to stay focused on patient care.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

Signature: [signature] VA License 0202205591 **Date:** 3/7/09

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Virginia Regulatory Town Hall

Logged in: DHP

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Virginia Board of Pharmacy Regulations [18 VAC 110 – 20]**

All comments for this forum

Commenter: Mary Scott Garrett, Parham Doctorsd' Hospital * 4/14/09

6955

I support the ammendment that would no lolnger requirethat nurses sign for controlled substances

that are added into automated dispensing machines. Most hospitals that have this system have an automated control tower, and reconciliation of dispensing is part of the job; this reconciliation step ensures that the correct amount gets to the correct place; if the correct amount is NOT added to the correct cabinet, the transaction stands out for the pharmacist to review.

Commenter: Jennifer Gaines, RN Martha Jefferson Hospital * 4/14/09

6956

Nurse signature for narcotic

I am for the petition is to allow Pharmacy to restock an AcuDose with narcotics WITHOUT a nurse having to sign for them. This practice is pulling nurses away form patient care for a poor quality measure. The practice shows little, i.e., what is the nurse truly signing?It simply shows that those narcotics numbers were present, but it does not verify the placement of them in the acudose. From a narcotic control perspective this shows nothing.

The count is independently and blindly verified for each and every entry for narcotics into the acudose, any discrepency is addressed with a miscount. If the narcotics were not placed in correct number by pharmacy, that would be addressed at the very next entry into that medication. The computer log would display who and what count was completed when.

The process of narcotic counts is important, but the current nurse signature effort doea not validate a correct count and is using valuable time for nurses...that could be spent in patient care.

Commenter: Brad Ferguson, CPhT Henrico Doctors' Hospital Forest Campus * 4/15/09

6959

Nursing signatures for narcotic delivery to automated dispensing systems

I absolutely agree with the proposed change that has been submitted regarding the requirement of a nurse's signature upon delivery of a narcotic by pharmacy staff. It is unnecessary to pull a nurse away from patient care in order to verify the count of narcotics that are being stocked into an automated dispensing system such as Pyxis or Acudose.

As previously stated by other participants of this petition, the signature of a nurse does not

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necessarily prove that the narcotics that were accounted for by that nurse made it to the dispensing mechanism. The pharmacy technician or pharmacist could theoretically get the signature from a nurse stating that the correct amount of drug was present, only to either mistakenly or purposely stock the machine incorrectly or not at all. Should a discrepancy arise, the only thing this requirement would do is complicate the situation by involving more employees in the problem. Also as before mentioned, if this does happen, the reports that are printed automatically for these systems will provide all pertinent information necessary to investigate the situation. The users who have previously accessed the drug in the dispensing unit will be the points of interest anyway, not the nurse who signed off on the dispensing sheet.

I know from personal experience that this additional step of acquiring a nurse's signature before restocking an Acudose or Pyxis machine is nothing more than an inconvenience to the nurses and potentially to the patients. With the nursing shortage that is at hand, I believe that many would agree that this is not a necessary state law, especially when the nursing staff is already stretched far too thin.

I have had many nurses posing the question to me, "Why do we have to sign off on these narcotics. You will be the last one with the drug. How do I know that you are going to put the right amount in the machine?" And I always agree with them. The only answer I can provide to them is that it is a Virginia state law. I don't think that answer is sufficient. This law does not make sense because it only delegates potentially great liability unto others unjustly. It does not seem to be beneficial in any way. I do not know of any situation in which the signature of a nurse for a narcotic being delivered to an automated dispensing machine has ever been used to determine the findings of a narcotic discrepancy. Yes, records for those signing out and delivering narcotics need to be maintained , but there is no need for records of a completely unassociated party when automation reports are more than sufficient.

This would be a great amendment if passed. I think it would be very beneficial to the healthcare professionals for whom this law affects, and more importantly, our patients. Thank you for presenting this issue for us to comment on. This is a great tool for resolving problems such as this that affect the healthcare community.

Commenter: Suzanne Garth,CPhT - Matha Jefferson Hospital * 4/16/09

6961

Nurses having to sign for controlled substances

As a technician who works the night shift, I know first hand how frustrating it is to have to take the time to find a nurse and pull her/him away from patient care when staffing is a shortage to sign th controlled substance form. I'm always asked why it must be signed ,since I'm the one stocking an a Pharmacist has already checked the amount dispensed.

I feel with the automated systems now installed and computerized reports that adequate records are available without having this extra sheet - which shows only that a nurse has signed - not the process.

Thank you for considering this change - which I feel will greatly improve the workflow.

I

Commenter: ryu chan hong * 4/17/09

6964

Subject: Details of the arrangements for the signature ceremony to be added once finalized

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Rulemaking Virginia

This Is Your Receipt

We have successfully received your order
We will ship as soon as we process your order.

Your Order Number = 1239845752-618425516

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It is a good idea to print this page for your records.

1239845752-618425516-101734300700R400-

Thank you.
The following message has been sent to the Governor:
(please print this page for your records)

From:

Mr. ryu chan hong
276 9 Yeon-dong
Cheju, VA 23210

rych67@gmail.com
Affiliation: Private Citizen
Subject: Details of the arrangements for the signature ceremony to be added once finalized

Message:
Rulemaking Virginia Notice of Intended Regulatory Action (NOIRA) **http://nrc-stp.ornl.gov/actionitems.html** 22-Dec-08 FSME-08-088 comment on proposed agreement between NRC and commonwealth of Virginia rev Details of the arrangements for the signature ceremony to be addec once finalized APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE Effective March 31, 2009 Virginia becomes the 36th Agreement State. The U.S. Nuclear Regulato Commission will transfer authority for the regulation of most radioactive materials used in Virginia the Commonwealth of Virgina. VDH's Division of Radiological Health is the radiation control agenc responsible for the implementation of the Agreement. 2.203 Settlement and compromise. Oriental Economic Institute (Keomgyosil) D-U-N-S No. 63-108-7863 Company Info 276 9 Yeon-dong Chej

Commenter: Denise Owczarski *

4/17/09
6966

VA rule 18 VAC 110-20 6.

I would like to state that I would like to see the rule that states a nurse must sign a for narcotics when being put in a automated dispensing unit disolved. It takes away time that the nurse can spend with patients and it takes up technician time that can be used in other ways.

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Commenter: Danielle Williams,CPhT *

4/18/09

6967

Nursing signatures for narcotic delivery to automated dispensing systems

Ive worked as a Pharmacy Technician in a hospital setting for years. As a day shift and a night sh position. I agree with the comments that have been made so far that state that obtaining a nursing signature when filling narcotics into a automated dispensing systems serves no real purpose. It holds up nurses from providing patient care and prevents technicians from moving to other machines on other units that need medications as well or from returning to the pharmacy to continue other important tasks. There are numerous reports that are kept by the systems that sho every transaction. These reports show far more than a RN signature. I would love to see this step removed from the process.

Commenter: Melanie Davies, CphT, Martha Jefferson Hospital *

4/19/09

6970

Nurses signing for narcotics for AccuDose/Pyxis Refill

I am absolutely for this petition as a technician who works the night shift solo with one pharmacist. It is very time comsuming and combersome to track a nurse down to sign for narcotics especially when they have no idea what you are going to do with them once they sign for them. The medication is signed out of NarcStation, which is accounting for the vault count, as well as stating where the drugs are going. The medication, as well as the count, is then verified by a pharmacist before delivery. Once the medication reaches the floor, we have to find a nurse willing to sign for the narcotics, then the count is added to the AccuDose/Pyxis, making for easy catch of a mistake, as it would be caught with the next AccuDose or Pyxis transaction. I feel with all the automation that we have in place, this paper trail is just a waste of paper, Pharmacy Technicians time, as well as Nurses time. I am constantly being asked "what exactly am I signing for", with a lot of hesitatio and disgruntlement.". This makes the process even longer because then I have to explain that is a state law, not a federal law, and that I absolutely agree with them that it is a waste of their time, a well as mine.

What they are verifying is that the count is correct, but is this really necessary? Isn't all of this eas tracked by NarcStation, the pharmacist signature, as well as the AccuDose/Pyxis machine? If the is a problem, it can always be solved with a transaction report. Why do the nurses need to be pulled away from their patients, when they are scarce and extremely busy, for this? I think this whole process should be reconsidered for everyone involved. It would greatly improve patient care as well as allow the pharmacy technician to deliver something to the floor in a timely manner.

Thank you for considering this change.

Commenter: Helen Shifflett Martha Jefferson Hospital Pharmacy *

4/20/09

6971

ISMP medication safety alert Volume 14 issue 7 - Nurses signing for narcotics

As a Pharmacy Technician I would like to say I think having the nurses sign for narcotics before restocking acu dose is a complete waste of time. I have NEVER had a nurse watch me restock. Some nurses don't even check the sheet they sign against the drugs I have, they just sign. IF I don't get something into the acu dose, who do you think will be held responsible? The Nurse? We

64

restock many other drugs that could be abused in some way, not just narcotics, and the nurses don't sign for them. Our Pharmacy is in the process of removing more Pharmacists from the Pharmacy to working on the floors. In short this means we will need our Techs in the Pharmacy more than ever. Thanks for your consideration, helen

Commenter: Courtney Fuller, Henrico Doctors' Hospital *

4/20/09

6972

Nursing Signature Required to verify loading controlled substances into ADC

I agree that it serves no purpose to pull nursing staff away from the bedside to sign for controlled substances that are being loaded into automated dispensing cabinets. They do not witness the transaction. The transaction is documented electronically by pass-coded entry into the automated dispensing cabinets. Additionally, the Board has requirements for auditing these processes. It is wasteful of both the technician's and nurse's time to continue this practice!

Commenter: Gena Harris- Martha Jefferson *

4/20/09

6973

Petition for Rulemaking

As a Pharmacy Technician, I feel that having the nurses sign for our narcotics is something that is not necessary. The nurses are busy taking care of patients, and patient care is much more important. Our narcotics are checked by a pharmacist before we deliver and we have to deliver in our acudose. I feel there is enough paper trail and computer trail that if a narcotic is not placed it w be caught with the next acudose transaction for that drug. I feel with this change we as technician and the nurses can be much more efficient in our jobs.

Commenter: Michael Ashby, M.D., Martha Jefferson Hospital *

4/21/09

6974

allow Pharmacy to restock an AcuDose with narcotics WITHOUT a nurse having to sign for them

I support this change. It serves little purpose to require the signature and takes time away from clinical care.

Commenter: NANCY STATON JOHN RANDOLPH HOSPITAL *

4/21/09

6975

NURSE SIGNATURES

THERE IS ALREADY A PAPER TRAIL STARTED WHEN THE PHARMACIST PULLS FROM THE ACUDOSE NARCOTIC CABINET. THEN THE TECHNICIAN FILLS THE NARCOTIC IN THE CORRECT ACUDOSE ON THE NURSING UNIT. THESE ACTIONS ARE REVIEWED EACH STEP OF THE WAY BY PAPER REPORTS PRINTED EVERY MORNING ,OR WHEN EVER

65

A QUESTION OR DISCREPANCY MAY ARISE.THE NURSES TAKING TIME AWAY FROM PATIENT'S

TO SIGN ANOTHER SHEET OF PAPER THAT IS NOT REALLY NEEDED IS UNFAIR TO THE

CARE SHE SHOULD GIVE HER PATIENTS.

Commenter: DEBI LIPSCOMB, JOHN RANDOLPH HOSPITAL * 4/21/09

6976

NURSES TO SIGN FOR NARCOTICS

ITS BEING VERIFIED BY THE TECHNICIAN AND THE PHARM. THAT DESPENCES IT FROM THE NARC STATION. THERE ARE NARC REPORTS PULLED DAILY TO VERIFY THE DESPENCING AND THE FILLING OF THE ACCUDOSE MACHINE SO NO I FEEL THAT THE NURSE DOESNT NEED TO SIGN FOR SOMETHING THEY ARE NOT WATCHING BEING PU INTO THE ACCUDOSE MACHINE..

Commenter: kathryn maggi, Centra health * 4/22/09

6978

nursing signing for control substance

Please allow Pharmacy to restock acudose machines with narcotics without a signature from a registered nurse. The time it takes to hunt one down and then they run from you because they don't want to sign it really annoing. The electronic trail leaves it hard for people in the pharmacy divert.

Commenter: Kathleen East, CPhT / Martha Jefferson Hospital 4/22/09

6980

I support the amendment to discontinue the collection of nurse's signatures.

This step is a redundant & unnecessary step that pulls the nurses, pharmacists, & technicians av from patient care. Also, this signature collection forces the technician to basically stand in the wa if the nurse's station is busy, which further detracts from patient care. Currently, there is a suffici paper trail between the withdrawl of narcotics out of the vault to the individual Pyxis/Acudose machine on the floors. And, these reports are reviewed daily already. Why continue to add to th unnecessary pile of papers for our pharmacists to review? The pharmacists have more pressing items, like patient care, to look at. Plus, we could be saving a lot of money by not having to buy tl paper & by just eliminating this step.

Commenter: TRACY PHILLIPS HENRICO DOCTORS HOSPITAL * 4/23/09

6984

NARCOTIC DELIVERY

I agree with the proposed rule change. Having nurses sign for narcotics takes nurses away from there main duty which is patient care. Their has been numerous occasions where a nurse has h to come from a patients room just to sign for the narcotics so I could put them in the accudose.

There is still a checks and balance system that is in place to insure that diversion of narcotics wil not happen. The computers will know if you didnt put in the correct amount. When then next person goes to take out a narcotic to give a patient the nurse will count prior and will see that the

is a discrepency.

I think that the proposed rule change would make nurses jobs better and easier as well as the pharmacy staff.

Tracy Phillips

Commenter: Elizabeth Roebuck Martha Jefferson Hospital * 4/23/09

6985

The nurses would have more time to spend with their patients

Commenter: LUCILLE TAYLOR, MARTHA JEFFERSON HOSPITAL * 4/23/09

6986

SUPPORT PROPOSAL

I suppport this proposal because the drugs being restocked in accudose or pyxis have already b checked by a pharmacist and the restocking can be verified through accudose and pyxis reporti This would free up the nurses to spend more time on patient care and make the technicians mo efficient because they would not waste time trying to track down a nurse to sign.

Commenter: Diana Moneymaker, CPhT,RPht Martha Jefferson Hospital * 4/23/09

6987

nurses signing for narcotics

Commenter: Amanda Wiggins, Henrico Doctors Hospital (Forest) * 4/23/09

6989

Nurses should not have to sign for narcotics that are being placed in automated dispensing devices.

I beleive that nurses should not have to sign for controlled substances that are being placed in automated dispensing devices in hospitals such as acudose, because not only does it take the nurses away from there patients it also holds up the pharmacy when a technician has to wait around a unit for a signature when other units are also waiting for narcotics to be loaded into the machines. As a technician who uses the Acudose machines on a regular basis the controlled substances get checked numerous times when the order is placed into the narcotic vault, when technician pull narcotics from the vault, then when the technician signs for them, and then agair when the pharmacist checks and signs for them before being dispenced into an acudose machi In my experience nurses are frustrated at having to be pulled away from work and often do not check what they are signing for and on evening and night shifts it is very difficult to even find a nurse who has a free hand and is not turning a patiend or busy elsewhere. Nurses also do not whitness the medications being put into the acudose machine to even ensure proper placement although the machine only allows the proper drawer and door to open for the narcotic that has b selected earlier to be dispenced from the narcotic vault located in the pharmacy. There are alre so many checks to ensure that the proper drugs are dispenced it is unnecessary to have a nurs

sign especially when it slows down the process of delivering medications that are needed right away.

Commenter: Linda Goff, Centra Health *

4/25/09
6991

Nurses signing for narcotics

I do not feel it is necessary to have a nurse sign for narcotics. All it basically says is taht the dru made it up to the floor. It does not assure anyone that the correct count was entered into the acudose machine.

In my opinion, it wastes the nurses's time and the pharmacy technician's time to have to track d a nurse and take them away from patient care.

Commenter: Heather Anderson, RPh Martha Jefferson Hospital *

4/25/09
6992

Nurses signing for narcotics

I fully support this amendment. I feel this task is very time consuming for nurses and pharmacy technicians alike. By taking away this mundane task our nurses have more time for patient care which is top priority.

Commenter: Alison Avance, Lynchburg Pharmacy *

4/27/09
6993

Pharmacy should not have to pull nurses to sign for narcotics.

Not only does it pull nurses away from patients, it also takes more time for pharmacy techiniciar find a nurse to sign for the controls. It is a hassle for both pharmacy and nurses. The controls a regulated enough to be accounted for if there was a discrepency.

Commenter: Sujatha Kemler Memorial Reginal Medical Center *

4/30/09
6996

Agree with Petition. Nurses should not be pulled away to sign the sheet.

Commenter: FRED HESS PHARMACIST MRMC *

4/30/09
6997

I SUPPORT ADMENTMENT

HAVING NURSES SIGN FOR NARCOTICS AFTER IS REDUNDANT WORK THAT TAKES TI AWAY FROM THE NURSES AND THE PHARMACY PERSONEL .

Commenter: Cecelia Ferguson RPh *

5/1/09
7000

I agree with omitting nurse signature for narcotics delivered to automated dispensing cabinets.

i support the change to regulations that would omit the requirement of a nursing signature for

narcotics which are delivered to an automated dispensing system, because the quantities dispensed and delivered are trackable thru the automated system, Thank you

Commenter: Mark Mayberry, Martha Jefferson Hospital *

5/1/09

7001

Change in practice

I am in favor of this change

Commenter: Mary Thweatt, HCA *

5/7/09

7005

petition

I agree with the petition that pharmacy should be able to re-stock narcotics WITHOUT a nurses signature.

Commenter: Kim B Hayes, Henrico Doctors' Hospital *

5/12/09

7030

In favor of petition to restock an AcuDose with controlled substances without nurse signature

I am writing to support the petition to allow pharmacy to restock an AcuDose with controlled substances WITHOUT a nurse signature. The controlled substance is signed out of stock in the pharmacy, verified by a pharmacist, and loaded into the AcuDose. Checks and balances exist to ensure that what was signed from the pharmacy is loaded into AcuDose. Requiring a nurse to s for the controlled substance does nothing more than pull the nurse away from patient care and create a delay in delivery by the pharmacy. There are also many nursing units that are closed o weekends or midnight shifts whereby obtaining a nurse signature requires shifting technician staffing to ensure nurse availability for signatures or create a delay in delivery until a nurse is scheduled to work.

The count for controlled substance is independently and blindly verified for each and every entry controlled substances into the AcuDose, any discrepancy is addressed within the shift. Audit tra exists for all AcuDose transactions. AcuDose access is limited to authorized users with confider and unique user id and passwords.

The control of scheduled medications is important but the current requirement for nurse signatu does not validate a correct count and is spending valuable time for nurses that should be spent patient care.

Back to List Comments

* Nonregistered public user

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Commenter: Emily Wells, Martha Jefferson Hospital *

I support the amendment

This amendment would allow technicians to deliver narcotics to the ER, ICU, etc in a timely manner and not have to pull nurses away from caring for their patients. Technicians are a key role in the pharmacy and having them return to the pharmacy in a timely manner instead of trying to search down a nurse to check their narcotics would allow them to come back and assist the pharmacist(s). This would be benificial to all! The narcotics are double check by a pharmacist before leaving the pharmacy and the acudose machines also have reports to assure the proper amount of narcotics were loaded.

BYLAWS OF THE VIRGINIA BOARD OF PHARMACY

ARTICLE I: GENERAL

The organizational year for the Board shall be from July 1st through June 30th. At the last meeting before July 1, the Board shall elect from its members a chairman and a vice chairman. The term of office shall be one year and shall begin on July 1. A person shall not serve as chairman or vice chairman for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

1. The officers of the Board shall be the chairman and the vice chairman
2. The chairman presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The chairman shall appoint all committees unless otherwise ordered by the Board.
3. The vice chairman shall act as chairman in the absence of the chairman.
4. In the absence, or inability to serve, of both the chairman and vice chairman, the chairman shall appoint another board member to preside at the meeting and/or formal administrative hearing.
5. The executive director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business shall be as follows:

1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.
2. Approval of Agenda
3. Public comment received
4. Approval of Minutes
5. The remainder of the agenda shall be established by the executive director in consultation with the chairman.

ARTICLE IV: COMMITTEES

A. There shall be the following standing committees:

Special Conference Committees
Examination Committee
Item Review Committee
Regulation Committee
Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The chairman may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chairman shall appoint committees as needed to expedite the adjudication of cases. These committees may also function as informal conference committees if a case involves a permit.

2. Examination Committee. This committee shall consist of four board members and the executive director. The Examination Committee shall meet as required to maintain the integrity, defensibility and current status of the Drug Law Examination. Additionally, the Board delegates to this Committee the approval of the Drug Law Examination for the purpose of licensure.

3. Item Review Committee. This committee shall consist of at least seven pharmacists holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of writing new items for the Drug Law Examination item bank.

4. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board's Public Participation Guidelines and any Executive Order of the Governor; and any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

5. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and robotic pharmacy systems and any matters related to such programs.

B. Ad Hoc Committees.
The chairman shall also name such other committees as may be deemed necessary.

C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.

2. The Board delegates to the executive director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.

3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.

4. The Board delegates to the Department of Health Professions' inspectors the authority to issue summaries of inspection deficiencies upon completion of an inspection, and the Board delegates to the executive director the authority to issue letters regarding reported deficiencies to the facilities or licensee.

5. The Board delegates to the executive director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

6. The Board delegates to the executive director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

7. The Board delegates to the executive director, in consultation with the chairman, the review and approval of applications for special or limited use pharmacy permits. If the executive director and chairman do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.

8. The Board delegates to the executive director, in consultation with the chairman, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the executive director and the chairman not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.

9. The Board delegates to the executive director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the chairman. Should the executive director and chairman not reach agreement, the matter shall be referred to a special conference committee.

10. The Board delegates to the chairman, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.

11. The Board delegates the approval of continuing education programs to the executive director in consultation with one member of the Board.

12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with §54.1-2408.1, to the executive director or deputy executive director. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with §54.1-2400 (13), to the executive director or deputy executive director. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the executive director or deputy executive director.

13. The Board delegates to the chairman, or the vice chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with §54.1-3307.3.

14. The Board delegates to the executive director, in accordance with §54.1-3434.1(A)(2), the authority to accept an inspection report or other documentation for a non-resident pharmacy from an entity that may not be listed on the Board's guidance document, or to request an inspection by an agent of the Board.

15. The Board delegates to the executive director the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

ARTICLE VI: AMENDMENTS

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date: July 1, 1997
Revised: October 9, 1997
August 17, 1999
June 13, 2001
September 15, 2004
June 7, 2005
September 13, 2005
June 5, 2006
June 10, 2009

COMMONWEALTH of VIRGINIA

Sandra Whitley Ryals
Director

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Richmond, Virginia 23233-1463

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MEMORANDUM

TO: Members, Board of Pharmacy

FROM: Sandra Whitley Ryals

DATE: May 21, 2009

SUBJECT: Revenue and Expenditure Analysis

Virginia law requires that an analysis of revenues and expenditures of each regulatory board be conducted at least biennially. If revenues and expenditures for a given board are more than 10% apart, the Board is required by law to adjust fees so that the fees are sufficient, but not excessive, to cover expenses. The action by the Board can be a fee increase, a fee decrease or maintain the current Board fees.

The Board of Pharmacy ended the 2006 - 2008 biennium (July 1, 2006 through June 30, 2008) with a cash balance of $1,135,650. Current projections indicate that revenue for the 2008-2010 biennium (July 1, 2008 through June 30, 2010) will exceed expenditures by approximately $213,208. When combined with the Board's $1,135,650 cash balance as of June 30, 2008 the Board's projected cash balance on June 30, 2010 is $1,348,858.

We recommend that no action to change license fees be taken at this time. This recommendation is based on the most current information and is subject to change.

We are grateful for continued support and cooperation as we work together to manage the fiscal affairs of the Board and the Department.

Please do not hesitate to call me if you have questions.

CC: Scotti Russell, Excutive Director
Mark Monson, Deputy Director of Administration
Charles Giles, Budget Manager
Elaine Yeatts, Senior Policy Analyst

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